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Evaluation of bioresorbable vascular scaffolds in acute coronary syndrome: A two-center, one-year follow-up analysis

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Abstract

Background: *Bioresorbable vascular scaffolds (BVS) have emerged as a new treatment option in cardiovascular medicine. Nonetheless, there is still limited data on the use of these novel devices in patients with acute coronary syndromes (ACS). The purpose of this study was to evaluate the feasibility and efficacy of BVS implantation in patients with ACS.*

Methods: *The present report is a prospective, two-center registry that involved 165 consecutive patients hospitalized with the diagnosis of ACS and treated with the Absorb BVS (Abbot Vascular, Santa Clara, USA). During 1-year, all patients were monitored for the following endpoints: death, myocardial infarction (MI), scaffold thrombosis (ST), target lesion revascularization (TLR), target vessel revascularization (TVR) and target vessel failure (TVF), defined as cardiac death, target vessel MI, and TVR.*

Results: *A total of 165 patients underwent 179 BVS implantations. 94 patients were diagnosed with unstable angina (UA; 57.6%), 45 with non-ST-segment elevation myocardial infarction (NSTEMI; 27.3%) and 26 with ST-segment elevation myocardial infarction (STEMI; 15.7%). Procedural success was achieved in all patients with thrombolysis in myocardial infarction flow 3. During a follow-up of 14.1 ± 8.5 months (median 12.4 months, IQR 8.7 [8.4 to 12.1] months) death occurred in 4 (2.4%) patients, including 2 (1.3%) cardiac deaths. There was only 1 case of subacute ST (0.66%), without late ST. The incidence of MI, TLR, TVR and TVF were: 2.65%, 2.65%, 7.95%, 9.3%, respectively.*

Conclusions: *The present results suggest that BVS implantation in ACS patients is feasible and safe in highly experienced centers. One-year clinical results are encouraging with a low rate of stent thrombosis.* (Cardiol J 2018; 25, 4: 479–486)

Key words: acute coronary syndrome, acute myocardial infarction, STEMI, NSTEMI, angiography, coronary, bioresorbable devices/polymers

Introduction

Currently, percutaneous coronary intervention (PCI) with drug-eluting stent (DES) implantation is recognized as the most effective treatment for the majority of patients with acute coronary syndrome (ACS) [1]. Despite improved long-term results, including death, myocardial infarction (MI), stent thrombosis and repeat revascularization, the placement of metallic stents may be associated with some limitations. Permanent presence of a metallic platform stimulates inflammatory and thrombotic reactions and this, in turn, increases predisposition to the development of coronary neoatherosclerosis and thrombosis [2, 3]. There is also an increased risk of acute and late stent malapposition due to stent undersizing, caused by vasospasm or thrombus sequestration behind

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the struts, especially in patients with thrombotic lesions [4–6]. Additionally, metallic stents exclude the possibility of future surgical revascularization of stented segments and may hinder non-invasive imaging techniques.

Efforts focusing on overcoming the foregoing disadvantages of permanent metallic stents allowed the introduction of the new technology of bioresorbable vascular scaffolds (BVS), which seems to be a huge step forward in cardiovascular medicine [7]. Since the first in-human drug-eluting BVS implantation, which took place in 2006, BVS have been shown to be safe and effective in stable patients with noncomplex lesions [8–11]. Nonetheless, there is still limited data on the use of these novel devices in patients presenting with ACS, the most pro-thrombotic form of atherosclerosis. Potential advantages of BVS implantation may be related to the future vessel lumen enlargement, plaque volume reduction and stabilization, vasomotion restoration as well as elimination of some of the triggers for very late stent thrombosis, such as the presence of non-endothelialized struts [12, 13]. On the other hand, the increased strut thickness of BVS delays endothelialization and correlates with flow disturbance [14], carrying an additional risk of scaffold thrombosis (ST) [14]. Another potential limitation of scaffolds is the increased risk of strut fracture and disruption due to overexpansion. For this reason, precise pre-dilatation and vessel sizing before BVS implantation and post-dilation following implantation should be performed, which may be hard to achieve in thrombotic lesions [15, 16].

The main purpose of this study was to evaluate the feasibility, safety and efficacy of BVS implantation in patients presenting with ACS.

Methods

The present report is a prospective, two-center registry involving consecutive patients hospitalized between December 2012 and October 2015 with the diagnosis of ACS treated with the implantation of BVS. Eligible patients had at least one significant coronary artery stenosis, with no restrictions as to the number, severity or lesion location. All patients underwent PCI with implantation of at least one BVS (Absorb, Abbott Vascular, Santa Clara, California). The main exclusion criteria were: the presence of cardiogenic shock, patient life expectancy of less than 1 year, the use of metallic stents during the index procedure and the target vessel reference diameter < 2.3 mm and > 3.7 mm by visual estimate. Detailed exclusion criteria are presented in Table 1.

Table 1. Exclusion criteria.

Known intolerance to acetylsalicylic acid, heparin, PLLA, everolimus, contrast material
Active bleeding or coagulopathy or patients on chronic anticoagulation therapy
Poor compliance
Cardiogenic shock
Comorbidity with limited expected survival (< 1 year)
Severe tortuous, calcified or angulated coronary anatomy of the study vessel
Fibrinolysis prior to PCI

PCI — percutaneous coronary intervention; PLLA — poly-L-lactide acid

The scaffold is composed of semicrystalline poly-L-lactide (PLLA) and coated with an amorphous poly-D, L-lactide (PDLA) polymer eluting everolimus, a potent antiproliferative drug. This fully bioresorbable scaffold is radio-lucent, thus 2 platinum markers are placed at each edge of the device to allow easy visualization on angiography or other imaging modalities [17]. The Absorb BVS is a thick-strut scaffold, with the average strut thickness of 157 microns. Currently three diameters (2.5, 3.0, 3.5 mm), and five lengths (8, 12, 18, 23, 28 mm) are available. The decision to use BVS was left to the discretion of the operator.

The PCI procedure was performed according to current PCI guidelines. Pre- and post-dilatation were at the discretion of the operator. The size of balloon for pre-dilatation was selected according to the reference vessel diameter (1:1). Scaffold sizing was based on the visual vessel evaluation. The implantation of a scaffold was performed with gradual pressure increase by 2 atm every 5 s without exceeding the rated burst pressure. During post-dilatation non-compliant, high-pressure balloons were used with a diameter sized 0.25–0.5 mm larger than the scaffold. Each patient naive to antiplatelet therapy, received a loading dose of 300 mg acetylsalicylic acid and 600 mg clopidogrel (n = 41; 24.8%) before or during PCI, followed by the maintenance daily dose of 75 mg of both medications or prasugrel 60 mg p.o. continued with 10 mg daily dose (n = 3; 1.8%) or ticagrelor 180 mg loading dose and continued with 2 × 90 mg daily dose (n = 121; 73.3%). Duration of dual antiplatelet therapy was recommended for a minimum of 12 months. Due to available data sug-

gesting that BVS may require prolonged dual antiplatelet therapy (DAPT), to mitigate the risk of late and very late ST, the decision about the continuation of DAPT after 12 months was made individually for the patient depending on the thrombosis risk.

A bolus of unfractionated heparin, 100 U/kg was administered intravenously during the procedure. The remaining pharmacotherapy was administered according to the contemporary guidelines.

The data related to baseline clinical characteristics, procedural and clinical events were collected on an electronic database. During the follow-up period, clinical data were obtained after 30 days, 6 months, 1 year and every following year by direct contact with patients or telephone interview, additionally, a review of medical reports if patients had been hospitalized.

Patients were monitored for the following endpoints: death, MI, ST, target lesion revascularization (TLR), target vessel revascularization (TVR) and target vessel failure (TVF), defined as cardiac death, target vessel MI, and TVR.

ST-segment elevation MI (STEMI) was defined as electrocardiographic ST elevation concomitant with characteristic symptoms of myocardial ischemia and subsequent release of biomarkers of myocardial necrosis [17]. ST-elevation was defined as new ST-segment elevation at the J point in two or more contiguous leads of > 0.1 mV in all leads other than leads V2–V3. For leads V2–V3 the following cut points apply: ≥ 0.2 mV in men ≥ 40 years, ≥ 0.25 mV in men < 40 years, or ≥ 0.15 mV in women. New or presumed new left bundle branch block has been considered as STEMI equivalent. Non-ST-segment elevation MI (NSTEMI) definition involved the presence of angina chest pain, with the marked elevation of biomarkers of myocardial necrosis with no evidence of ST-segment elevation in the electrocardiogram (ECG). Unstable angina was considered to be present in patients with symptoms of myocardial ischemia and no troponin elevation, with or without ECG changes indicative of ischemia (e.g., ST segment depression or transient elevation or new T wave inversion) [18]. Death was defined as all-cause mortality during the follow-up period. The ST was defined according to the Academic Research Consortium definition [19, 20]. TLR was defined as target segment reintervention including 5 mm proximal and distal to the scaffold. Revascularization was considered clinically indicated if symptoms of myocardial ischemia were present, and/or positive stress test, electrocardiographic evidence of ischemia at rest, and/or > 70% diameter in-lesion stenosis on angiography were observed.

Angiographic success was defined as successful scaffold deployment at the intended site with the residual stenosis of less than 30% (visual estimation), with thrombolysis in myocardial infarction (TIMI) flow grade 3. Procedure success was defined as angiographic success in the absence of in hospital major adverse cardiac events (MACE).

Statistical analysis

Continuous variables are presented as mean ± standard deviation or median (interquartile range [IQR]) and categorical variables are presented as counts and percentages. The Kaplan-Meier method was used to generate cumulative incidence curves for composite endpoint. Analysis was carried out using the Statistica software, version 13 (StatSoft Poland).

Results

A total of 165 ACS patients were treated with a total of 179 BVS implantation within the study period between October 16, 2012, and October 25, 2015. Of these, 94 patients were diagnosed with unstable angina (57.6%), 45 with NSTEMI (27.3%) and 26 with STEMI (15.7%). Detailed demographic and clinical patient characteristics are presented in Table 2.

Procedural success was obtained in all patients. In 3 cases coronary dissection occurred and was successfully covered with an additional scaffold. No peri-procedural MACE were reported. Pre- and post-dilatation were performed in 94% and 81% of patients, respectively. The angiographic characteristics of the lesions treated and the procedure are reported in Table 3.

Complete follow-up was available in 93% of patients (n = 151), however data concerning death were obtained from province governor's office for all patients. The mean time of observation was 14.1 ± 8.5 months (median 12.4 months, IQR 8.7 [8.4 to 12.1] months). During this period 4 patients died (2.42%), 2 of cardiovascular cause. Four patients developed recurrent MI (2.65%), 2 in hospital (1 with new Q wave formation), and the other 2 within 6 months (1 STEMI and 1 NSTEMI). In 3 cases MI's were related to the target vessel. The composite rate of TVF was 9.3%. The rate of TLR and TVR was 2.65% (n = 4), 7.95% (n = 12), respectively. ST occurred in 1 (0.66%) patient during hospitalization (definite sub-acute thrombosis). No more ST occurred at follow-up (Table 4).

Table 2. Baseline characteristics.

Age	59.9 ± 10.6
Male	124 (75.1%)
STEMI	26 (15.7%)
NSTEMI	45 (27.3%)
Unstable angina	95 (57.6%)
Cardiovascular history:	
Prior MI	44 (26.7%)
Prior PCI	53 (32.1%)
Prior CABG	8 (4.8%)
Stroke	8 (4.8%)
Cardiovascular risk factors:	
Hypertension	138 (83.6%)
Diabetes mellitus	36 (21.8%)
IDDM	11 (6.7%)
Hyperlipidemia	138 (83.6%)
Smoking, current	67 (40.6%)
Heart failure	77 (46.7%)
NYHA:	
I	28 (16.9%)
II	31 (18.8%)
III	13 (7.9%)
IV	5 (3%)
Peripheral artery disease	16 (9.7%)
Chronic kidney disease (eGFR < 60)	13 (7.9%)
LVEF < 50%	42 (25.4)

Depicted are counts, number, incidence (%) or mean ± standard deviation; CABG — coronary artery bypass grafting; eGFR — estimated glomerular filtration rate; IDDM — insulin dependent diabetes mellitus; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; NYHA — New York Heart Association, PCI — percutaneous coronary intervention; STEMI — ST-segment elevation myocardial infarction

Table 3. Angiography characteristics.

Single vessel disease	85 (51.5%)
Multivessel disease	81 (49.1%)
Target vessel location:	
LM	7 (4.2%)
LAD	81 (49.1%)
RCA	29 (17.6%)
LCX	33 (20.0%)
Other	18 (10.9%)
Lesion type:	
B1	10 (6.1%)
B2	142 (86.1%)
C	4 (2.4%)
Calcification	9 (5.5%)
Bifurcation lesion	20 (12.1%)
Thrombus	12 (7.3%)
Restenosis	5 (3.0%)
RVD [mm]	2.9 ± 0.3
MLD [mm]	0.1 ± 0.2
Diameter stenosis [%]	88.4 ± 0.07
IVUS	4 (2.4%)
OCT	0 (0%)
QCA	12 (7.3%)
Visual estimate	150 (90.9%)
Total number of scaffolds	179
Mean scaffolds per lesion	1.1
Mean scaffold length per lesion	21.0 ± 7.9
Mean scaffold diameter per lesion	3.0 ± 0.4
Radial approach	50 (30.3%)
Pre-dilatation	154 (94.0%)
Mean pre-dilatation balloon diameter [mm]	2.7 ± 0.4
Max pre-dilatation pressure [atm]	12.8 ± 2.0
Post-dilatation	133 (81%)
Mean post-dilatation balloon diameter	2.9 ± 0.6
Max post-dilatation pressure [atm]	18.4 ± 2.8
Pre-procedure TIMI-flow:	
0–1	58 (34.9%)
2	50 (30.3%)
3	58 (34.9%)
Post-procedure TIMI-flow:	
0–1	0 (0%)
2	5 (3.0%)
3	160 (97.1%)
In-scaffold (visual estimate):	
Mean lumen diameter	2.8 ± 0.3
MLD	3.0 ± 0.4
Diameter stenosis	0.3 ± 0.01
Complications occurring any time during the procedure:	
MACE	0 (0%)
Dissection	3 (1.8%)
Spasm	0 (0%)
Distal embolism	0 (0%)
No-reflow	0 (0%)
Angiographic success	165 (100%)
Procedure success	165 (100%)

Depicted are counts, number, incidence (%) or mean ± standard deviation; IVUS — intravascular ultrasound; LAD — left anterior descending artery; LCX — left circumflex artery; LM — left main; MACE — major adverse cardiac events; MLD — minimal lumen diameter; OCT — optical coherence tomography; RCA — right coronary artery; RVD — reference vessel diameter; TIMI — thrombolysis in myocardial infarction; QCA — quantitative coronary angiography

Discussion

The results of this study showed a high device and procedural success rate, with a relatively low incidence of peri-procedural complications in ACS patients treated with BVS. Also 1-year results are excellent in this group of patients.

The use of bioresorbable scaffolds in ACS patients carries some risks. Correct vessel and scaffold sizing is very important, due to device expansion limits, but correct assessment of target vessel diameter may be difficult due to spasm or the presence of thrombus [21]. Aggressive lesion preparation increases the rate of successful device delivery and correct expansion, thus pre-dilatation is advisable in all patients [22]. However, in settings of ACS such maneuvers carry additional risk

Table 4. Results.

N = 151	FU < 30 days	Total FU
All cause death	1 (0.61%)	4 (2.42%)
Cardiac death	1 (0.61%)	2 (1.21%)
Any MI	2 (1.32%)	4 (2.65%)
Target vessel MI	2 (1.32%)	3 (1.98%)
Scaffold thrombosis	1 (0.66%)	1 (0.66%)
Target lesion revascularization	2 (1.32%)	4 (2.65%)
Target vessel revascularization	3 (1.98%)	12 (7.95%)
Target vessel failure	4 (2.65%)	14 (9.27%)

Depicted are counts, number, incidence (%); MI — myocardial infarction, FU — follow-up

of plaque disruption, thrombus mobilization and distal embolism. For this reason, in highly thrombotic lesions, thrombus aspiration prior to balloon inflation seems mandatory [23]. In the present study pre-dilatation was performed in as many as 94% of patients, including 12 cases with thrombus visible on angiography. In all these cases, manual thrombus aspiration was applied prior to pre-dilatation. The overall procedural success rate was 100%, including all cases with evident thrombus. Additionally, the presence of thrombus increases the risk of acute, as well as late scaffold malapposition. However, in the prospective, multi-centre Prague 19 study, the optical coherence tomography (OCT) analysis revealed only 1.1% of malapposed struts, much less than the number observed in the Absorb Cohort B study (3.5%) [24, 25]. Currently, the most reliable method of vessel sizing is OCT, which provides precise vessel and lesion measurements, optimal for sizing and positioning of the scaffold. Moreover, OCT allows for accurate assessment of scaffold apposition after completion of the procedure. However, due to limited availability and costs, OCT is generally underused. When quantitative coronary angiography analysis alone is applied, maximal vasodilatation with intracoronary nitroglycerin injection should be obtained prior to measurement. In this study only visual estimations have been applied, which represents a typical clinical approach in an all-comer population of ACS patients. The present results showed that the procedure of BVS implantation, especially regarding to pre-, post-dilatation and vessel sizing, can be safe and effective when it is performed by very experienced operators.

The rate of post-dilatation in this series was high (81%), which corresponds to the current opinion of a majority of operators. Post-dilatation should be performed with short non-compliant balloons, for at least 10–30 s [22].

In randomized trials mid and long-term outcomes of PCI procedures with BVS have been assessed predominantly in patients with stable coronary disease and relatively simple lesions [25–29]. Recently, the preliminary report of prospective has been published, randomized all-comer AIDA trial (Amsterdam Investigator–initiateD Absorb strategy all-comers trial) which evaluated the efficacy and performance of Absorb BVS strategy versus XIENCE family everolimus-eluting metallic coronary stent system in the treatment of coronary lesions. There was no significant difference in the rate of TVF between the scaffold versus stent strategy (2-year cumulative event rates, 11.7% and 10.7%, respectively; hazard ratio [HR] 1.12; 95% confidence interval [CI] 0.85–1.48; $p = 0.43$). However, the bioresorbable scaffold was associated with a higher incidence of device thrombosis (31 patients) than the metallic stent (8 patients) through 2 years of follow-up (2-year cumulative event rates, 3.5% vs. 0.9%; HR 3.87; 95% CI 1.78–8.42; $p < 0.001$) [29]. As opposed to randomized trials, registries bring more light to the value of bioresorbable technology in all-comer populations, including patients with ACS. In the GHOST-EU, the largest all-comer registry to date, BVS proved to be effective in a wide range of patients, including 563 patients with ACS. At 6 months the incidence of target lesion failure (TLF, composite of cardiac death, target-vessel MI, or clinically driven TLR) reached 4.4%. The rate of Academic Research Consortium (ARC) definite/probable ST (1.5% at 30 days and 2.1% at 6 months) was higher when compared to other BVS and DES studies [30]. It should be noted that this study reflects a very early experience of European operators with bioresorbable technology, with an overall post-dilatation rate below 50%. The results varied widely between centers, mainly due to differences in center experience. The outcomes in highly experienced centers were definitely better. Notably, the use of intravascular imaging tools was relatively rare in the GHOST-EU Registry, which might essentially affect outcomes.

A recent large registry published by Puricel et al. [31], reported data following BVS implantation in 1305 unselected patients, including 653 (50%) patients presented with ACS (19% STEMI),

has shown similar results. The rate of probable and definite ST was 1.8% at 30 days, 2.3% at 6 months, and 3.0% at 12 months. In a multivariable analysis, impaired left ventricular function ($p = 0.019$) and BVS implantation in ostial lesions ($p = 0.049$) were independently associated with ST. In addition, post-procedural minimal lumen diameter (MLD) and reference vessel diameter were significantly lower in the ST group ($p < 0.001$ for both). Authors reported that post-procedural MLDs below 2.4 mm (for the 2.5-mm to 3.0-mm BVS) and 2.8 mm (for the 3.5-mm BVS) were associated with an increased risk of thrombosis. Interestingly, the implementation of a BVS-specific implantation procedure significantly decreased the incidence of 12-month ST from 3.3% to 1.0% ($p = = 0.035$). After propensity score analysis ("early experience" group vs. "BVS-specific protocol" group) this result was maintained ($p < 0.012$) [31]. ACS patients form a special group, where the main concern is the implantation of thick-strut devices into lesions with high thrombus burden [32]. Diletti et al. [23] presented promising clinical results of BVS implantation in 48 STEMI patients at the 30-day follow-up. The overall MACE rate was only 2.6%, including 1 patient, who developed a non-Q wave MI related to a non-target-vessel [23]. Similarly, the Prague 19 study has shown high efficacy and safety of BVS implantation in STEMI as compared to a control group treated with metallic stents. Out of 41 patients treated with BVS at 6 months there were only 2 (5.0%) events (1 ST in a patient who stopped taking all the prescribed medications and a small MI due to intra-procedural side branch occlusion), whereas there were 4 (7.02%) events in the control [24]. Another registry reported the use of BVS in real-world setting. In the Polish National Registry, data from 30 interventional centers in Poland were collected. Out of 591 patients 52% presented with ACS. The results have shown high procedural success and a low complication rate with dissection in 2.9% of patients, slow-flow in 0.5%, no-reflow in 0.17%, and side branch occlusion in 0.33% [33]. The POLAR ACS study analyzed 100 patients with ACS treated with BVS implantation. At 1-year, 1 MI caused by ST as well as 1 TLR were observed [34]. For comparison, the outcomes of an all-comers registry have shown the relatively high incidence of definite/probable ST (3.1% at 12 months, all in the first 6 months) in the setting of ACS (37.6% of STEMI). The rate of composite endpoint (cardiovascular death, any MI, TLR) reached 13.5%, including 4 (3%) cardiac deaths, 4 (3%) STEMIs, 5 (3.8%) NSTEMIs, 9 (6.8%) TLRs, and was comparable with all-comer DES studies, enrolling ACS patients [35–39]. The majority of events occurred in the first 6 months [40]. Imori et al. [41] have showed that in the setting of ACS patients the rates of MACE (composite of death, myocardial infarction, TLR) (9.3% vs. 4.7%, $p = 0.003$) and stent thrombosis (2.8% vs. 0.9%, $p = 0.01$) were significantly higher in BVS group compared to EES group. However, the authors noticed that the incidence of MACE in BVS patients with postdilatation was comparable to those observed in EES group (6.0% vs. 4.7%, $p = 0.23$). These differences were mainly driven by lower rate of TLR. ST rate was also decreased, but not significantly (2.6% vs. 0.9%, $p = 0.045$). In comparison to presented data, these results are promising. ST occurred in only 1 (0.66%) patient, and the composite rates of TVF was 9.3% at 1-year follow-up. Recent evidence from clinical trials have shown similar outcomes.

The 3-year ABSORB II study has had a critical impact on BVS technology and has undermined its current state of development [28]. The treatment with Absorb was associated with a 2-fold increased risk of device-oriented clinical events, specifically an increased risk of target-vessel MI (7% vs. 1%; $p = 0.006$), as well as increased risk of late ST compared with Xience (Abbott Vascular). The definite ST occurred in 6 patients who received the Absorb compared with no reported cases of definite or probable stent thrombosis for patients who received the Xience stent. Additionally, Absorb did not result in an improvement in vasomotor tone and was associated with an increase in late lumen loss when compared with the Xience everolimus-eluting metallic stent. The question is what has beenlearned from this lesson and what direction of development should now be chosen.

Regarding conclusions from the BVS, every new device should undergo monitored introduction and be limited to strictly selected patient groups. The uture direction for research in BVS technology should be focused on several aspects. Reduction of strut thickness and introduction of rounder strut cross-section will reduce the protrusion of the strut and minimize areas of flow disturbance as well as recirculation zones. Moreover, faster bioresorption without inducing an inflammatory vasculitis will result in fast tissue coverage and firm encapsulation of the struts into the vessel wall. As a result, thrombogenicity could be decreased. Research on the second generation of BVS is underway.

The results of the present study demonstrated the procedural feasibility and efficacy as well as

clinical safety of BVS implantation in patients presenting with ACS. Nonetheless, due to concerns regarding long-term clinical safety all patients after BVS implantation should be closely monitored. Additionally, data from ongoing trials should be made available in the public domain at regular intervals.

Limitations of the study

The present findings are mostly limited by the observational nature of a prospective, single-arm study. Head-to-head comparison was not performed with the standards of treatment. Additionally, the follow-up period differed between patients with no minimal observation time. The presented clinical outcomes are encouraging, but require longer follow-up.

Conclusions

The use of BVS in the documented centers were feasible in most patients with ACS. One-year clinical results are encouraging and were comparable to outcomes reported in patients implanted with second-generation DES. Notably, all patients were treated in two highly experienced centers.

Conflict of interest: Aleksander Araszkiewicz, Stefan Grajek, Maciej Lesiak — grants from Abbott Vascular.

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